APR 2 7 2005

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510 (k) Summary

1. **Date Prepared:** January 24, 2005

2. **Submitter**

Covalon Technologies Inc.
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Mississauga, L4Z 3E6
Ontario, CANADA
Tel: (416) 944.3496
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Submission Correspondent:

Paul L. Guilbaud
Vice President and Director Wound & Tissue Repair

14510 Kandi Court
Largo, Florida 33774
Tel: (727) 595.8184
Fax: (727) 517.7005
Email: pguilbaud@covalon.com

4. **Proprietary Name:** ColActive™ Collagen Wound Dressing

Common Name: Wound Dressing

5. **Regulatory Class:** FRO

6. **Statement of Substantial Equivalence:**

ColActive™ Collagen Wound Dressings are substantially equivalent in materials of construction and intended use and identical in function to FIBRACOL PLUS Collagen Wound Dressing with Alginate manufactured by Johnson & Johnson Medical and SkinTemp Kollagen Wound Management Material manufactured by Biocore Medical Technologies.

7. **Indications For Use:**

ColActive™ Collagen Wound Dressing is indicated for the management of full and partial thickness wounds including:

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- Pressure ulcers
- Diabetic ulcers

- Ulcers caused by mixed vascular etiologies
- Venous ulcers
- Second degree burns
- Donor and graft sites
- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

8. Description:

ColActive™ Collagen Wound Dressing is an advanced wound care dressing composed of collagen and sodium alginate provided in a sterile sheet or rope form. ColActive™ Collagen Wound Dressings are pliable, absorbent dressings that absorb moisture such as wound fluid forming a gel, thus maintaining a moist environment at the wound surface that aids in the formation of granulation tissue and epithelialization. The dressings can be cut to fit specific wounds and are able to be layered for the management of deep wounds.

9. Biocompatibility:

ColActive™ Collagen Wound Dressings have been demonstrated to be safe wound dressings. To support the biocompatibility of these products, safety tests were conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices.

When all test results from tests conducted on ColActive™ Collagen Wound Dressings are taken into consideration as a whole, ColActive™ Collagen Wound Dressings have been demonstrated to be safe topical wound dressings in accordance with ISO 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

Mr. Paul L. Guilbaud
Vice President Wound and Tissue Repair
Covalon Technologies, Inc.
14510 Kandi Court
Largo, Florida 33774

Re: K050177
Trade/Device Name: ColActive™ Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: March 29, 2005
Received: March 31, 3005

Dear Mr. Guilbaud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050177

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510 (k) Number: k050177
Covalon Technologies, Inc.

Device Name: ColActive™ Collagen Wound Dressing

Indications for Use:

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- Pressure ulcers
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- Abrasions
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- Traumatic wounds healing by secondary intention

Prescription Use √ OR Over-the-Counter Use___
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible] (OD)
[illegible] of General, Restorative
[illegible] Neurological Devices

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